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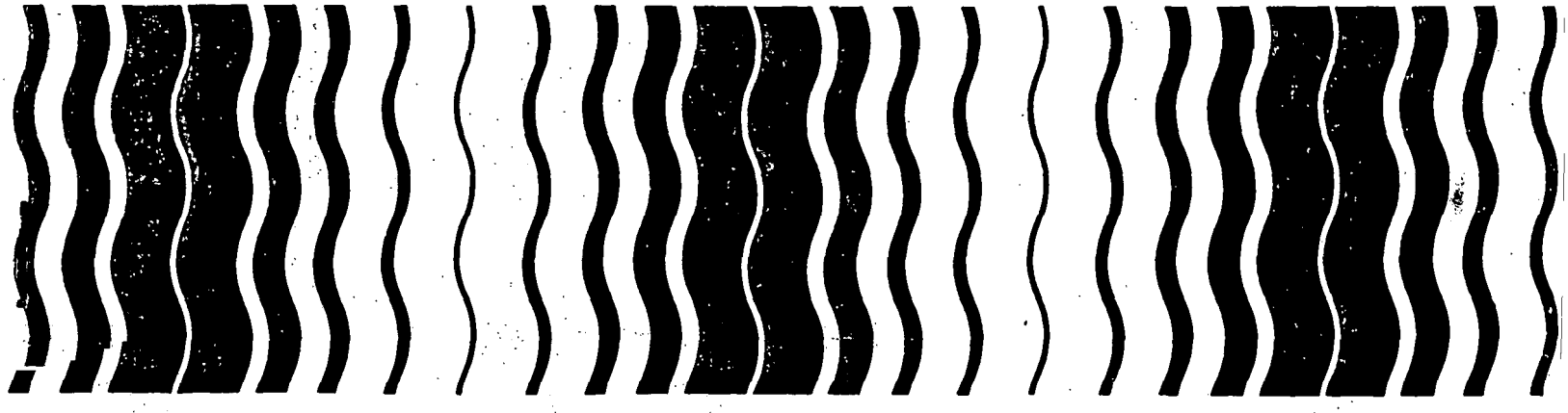
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing CHLORINATED ISOCYANURATES as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

CHLORINATED ISOCYANURATES

AS THE ACTIVE INGREDIENT

CASE NUMBER 0569

CAS REGISTRY NUMBER 2782-57-2
EPA/OPP PESTICIDE CHEMICAL CODE 081401

CAS REGISTRY NUMBER 2244-21-5
EPA/OPP PESTICIDE CHEMICAL CODE 081403

CAS REGISTRY NUMBER 2893-78-9
EPA/OPP PESTICIDE CHEMICAL CODE 081404

CAS REGISTRY NUMBER 87-90-1
EPA/OPP PESTICIDE CHEMICAL CODE 081405

CAS REGISTRY NUMBER 30622-37-8
EPA/OPP PESTICIDE CHEMICAL CODE 081406

CAS REGISTRY NUMBER 51580-86-0
EPA/OPP PESTICIDE CHEMICAL CODE 081407

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OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

ENVIRONMENTAL PROTECTION AGENCY

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request1/, focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard,

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1/ The scientific reviews may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703/487-4650).

on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, EPA may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of continued studies called in by the Agency and continues as long as a product is registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of Chemical

The following chemicals are covered by this registration standard:

1. Common Names: Dichloro-s-triazinetrione, dichloroisocyanuric acid.

   Chemical Name: 1,3-Dichloro-s-triazine-2,4,6 (1H,3H,5H) trione.

   CAS Registry No: 2782-57-2.

   EPA/OPP Pesticide Chemical Code: 081401.

   Empirical Formula: $C_3HN_3O_3Cl_2$.

   Trade Name: ACL 70.

2. Common Names: Potassium dichloro-s-triazinetrione; Potassium dichloroisocyanurate.

   Chemical Name: 1,3-Dichloro-s-triazine-2,4,6 (1H,3H,5H) trione potassium salt.

   CAS Registry No: 2244-21-5.

   EPA/OPP Pesticide Chemical Code: 081403.

   Empirical Formula: $C_3N_3O_3Cl_2K$.

   Trade Names: ACL 59; P.D.I.C.

3. Common Names: Sodium dichloro-s-triazinetrione; Sodium dichloroisocyanurate.

   Chemical Name: 1,3-Dichloro-s-triazine-2,4,6 (1H,3H,5H) trione sodium salt.

   CAS Registry No: 2893-78-9.

   EPA/OPP Pesticide Chemical Code: 081404.

   Empirical Formula: $C_3N_3O_3Cl_2Na$.

   Trade Names: ACL 60; CDB 60; CDB 63; S.D.I.C.

4. Common Names: Trichloro-s-triazinetrione; trichloroisocyanuric acid; trichloroisocyanurate.

   Chemical Name: 1,3,5-trichloro-s-triazine-2,4,6 (1H,3H,5H) trione.

   CAS Registry No: 87-90-1.

   EPA/OPP Pesticide Chemical Code: 081405.

   Empirical Formula: $C_3N_3O_3Cl_3$.

   Trade Names: ACL 90 Plus; CDB 90; T.I.C.A.; TCCA.

5. Common Name: Penta-s-triazinetrione.

   Chemical Name: [Mono-(1,3,5-trichloro)tetra (1-potassium-3,5-dichloro)] penta-s-triazinetrione.

   CAS Registry No: 30622-37-8.

   EPA/OPP Pesticide Chemical Code: 081406.

   Empirical Formula: $(C_3N_3O_3Cl_2K)_4.C_3N_3O_3CL_3$.

   Trade Names: ACL 66; DS.

6. Common Names: Sodium dichloro-s-triazinetrione dihydrate; sodium dichloroisocyanurate dihydrate.

   Chemical Name: 1,3-Dichloro-s-triazine-2,4,6 (1H,3H,5H) trione sodium salt dihydrate.

   CAS Registry No: 51580-86-0.

   EPA/OPP Pesticide Chemical Code: 081407.

   Empirical Formula: $C_3N_3O_3Cl_2N_2.2H_2O$.

   Trade Names: ACL 56; CDB Clearon; DICD.

The dechlorinated s-triazinetrione, isocyanuric acid, is not being considered for reregistration under this standard since it has no pesticidal properties *per se*. It acts only as an inert chemical stabilizer for the hypochlorous acid derived from other sources.

Description of Physical Characteristrics of Chemicals:

Color: White.

Physical State: Crystalline Solid.

Odor: Slight odor of chlorine.

Melting Point: 225-250° C with decomposition.

Bulk Density: Powder, 0.50-0.65 g/ml; regular, 0.82-1.0 g/ml; granular, 0.85-0.96 g/ml; extra granular, 0.92-0.95 g/ml.

Solubility: Dichloro-s-triazinetrione, 0.8 g/100 g water at 25°C; potassium dichloro-s-triazinetrione, 9 g/100 g water at 25°C; sodium dichloro-striazinetrione, 24.8 g/100 g water at 26.8°C; trichloro-s-triazinetrione, 1.2 g/100 g water at 25°C; penta-s-triazinetrione, 2% in water at 30°C; sodium dichloro-s-triazinetrione dihydrate, 26.2 g/100 ml water at 25°C.

Vapor Pressure: Very low, impossible to measure.

Stability: Stable and relatively inert when dry.

B. Use Profile

Type of Pesticide: Disinfectant; sanitizer; algaecide; fungicide.

Pests Controlled: Bacteria; algae; slime forming microorganisms; mold and mildew.

Registered Uses: Swimming pools; industrial water cooling systems; oil recovery systems; sewage systems; industrial preservatives; food processing/service industries; laundry sanitizer uses; household areas; mold and mildew; egg sanitizing and poultry drinking water sanitization.

Predominant Uses: Major use is swimming pools (74%). Minor uses include recirculating cooling water systems and food contact surface and laundry sanitizers.

Mode of Activity: Disinfection/Sanitization.

Formulation Types Registered: Solids; aqueous dilutions.

Method of Application: Added as solids to swimming pools or industrial cooling water systems; aqueous solutions applied by mopping, scrubbing, flooding, sponging, spraying and immersing to food and non-food contact surfaces.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all of the data submitted to support the registration of the chlorinated isocyanurates, as well as open literature information relevant to these chemicals. Based on a review of these data, EPA has reached the following conclusions.

Isocyanurate related effects observed in subchronic studies included hyperplasia of the urinary blader and calculi in male mice and hyperplasia of the lining of the urinary bladder in male rats. In a chronic study in rats, toxicity secondary to formation of calculi in the kidney and urinary bladder was observed in the male rats during the first 12 months of dosing at 5375 ppm. No effects were observed at 2400 ppm. No oncogenic effects were observed in lifetime studies in mice and rats. The chlorinated isocyanurates do not induce reproductive effects in rats, teratogenic effects in rats or rabbits, and are not mutagenic. The chlorinated isocyanurates have low oral and dermal toxicity and high primary eye irritation toxicity. The chlorinated isocyanurates are slightly toxic to birds, but are acutely toxic to fish and invertebrates.

There are no significant human toxicological data gaps for the chlorinated isocyanurates; only a primary eye irritation study is required for the trichloroisocyanurate group. The chronic effects from these chemicals to aquatic organisms are not fully known, however.

The hypochlorous acid derived from the chemical reaction of the chlorinated isocyanurates and water has been shown to be chronically toxic to marine and estuarine invertebrates and fish. A residue monitoring study is being required to measure the exposure and risk of hypochlorous acid to aquatic organisms.

There are no environmental fate data gaps for the chlorinated isocyanurates. Available hydrolysis data and the required residue monitoring study for hypochlorous acid will adequately characterize the environmental fate of the chemicals covered under this standard.

B. KIDNEY TOXICITY ISSUE

The original toxicological data base for the registration of the isocyanurates was based on studies performed in Industrial Biotest Laboratories (IBT). Although these studies were later invalidated, the IBT chronic rat study indicated that the compound produced kidney toxicity.

Since the public is widely exposed to isocyanurates through their use in swimming pools, EPA presented the information available at the time to the FIFRA Scientific Advisory Panel (SAP) for their opinion. At an open meeting held in Arlington, Virginia (January 17-18, 1980), the SAP completed a review of the health risks associated with the use of the chlorinated isocyanurates. (Fowler, 1980)*

The SAP concluded that the wide exposure of these compounds in the environment, coupled with an inadequate data base from early toxicity studies, were causes for concern to the panel. For these reasons, the SAP recommended an immediate coordinated attempt by EPA and the chlorinated isocyanurate industry to establish, if possible, whether these compounds are toxic to the kidney. In addition to the prompt initiation of investigative procedures for the definition of hazards, the SAP indicated that the adoption by EPA of an appropriate posture for expeditious regulatory action, should it be necessary, was fully warranted. The SAP recommended that additional contemporary assays to characterize the safety of the chlorinated isocyanurates should be undertaken using currently accepted protocols, including carcinogenic, mutagenic and teratogenic assays.

In response to these conclusions, EPA issued a Data Call-In Notice in accordance with section 3(c)(2)(B) of FIFRA. This notice required that the registrants of chlorinated isocyanurates perform the animal studies recommended by the SAP. Reports of these studies have been received and evaluated for this standard.

The subchronic rat and mouse studies and the chronic rat study reviewed in the development of this standard provide acceptable data for evaluating the kidney toxicity of the chlorinated isocyanurates. In these studies sodium isocyanurate was administered in the animals' drinking water at doses up to and including the limit of solubility of the compound (5375 ppm) at pH 7.

In the subchronic mouse study, the only compound-related effect was bladder calculi in two male mice at the high dose, associated with irritation of the bladder lining (LOEL 5375 ppm, NOEL 1792 ppm). The subchronic rat study showed hyperplasia of the lining of the urinary bladder in the males (LOEL 1792 ppm, NOEL 896 ppm). No effect was observed in the kidneys of either sex.

The chronic rat study provided significant information on kidney toxicity. Compound-related gross and microscopic lesions were found in the urinary tract and heart, primarily

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* Memo, H.W. Fowler, Advisory Report on Chlorinated Isocyanurates, February 15, 1980.

in males that died during the first 12 months of the study after receiving 5375 ppm. Acute nephrosis and chronic progressive nephropathy in the kidneys and inflammation, hemorrhage and epithelial hyperplasia of the urinary bladder in these males was considered related to calculi found grossly in the kidney and bladder. Lesions in the heart, inflamation (myocarditis and endocarditis), necrosis, and vascular mineralization were secondary to the uremia caused by urinary tract lesions. The LOEL for the study was 5375 ppm based on decreased survival in males and lesions in the urinary tract and heart; the NOEL was 2400 ppm (154 mg/kg/day).

The solubility of sodium isocyanurate and isocyanuric acid in water at 25°C has been established as follows: (Nelson, 1979)*

	mg/liter(ppm)	
pH	Sodium Cyanurate	Cyanuric Acid
4.4	4300	3700
7.2	8700	7400
7.7	8100	6900
8.6	7600	6500

Considering that the high dose sodium cyanurate was ingested with the drinking water at saturation for pH 7 and excreted in the urine at a pH in the order of 4.4 where its solubility is considerably less, precipitation and calculi may form in the urine. This possibility was clearly observed in the male rats at the high dose of the chronic study, but not in the females. The male rat tends to retain a portion of urine in its bladder at urination while the female voids entirely. This retention favors calculi formation. Thus, the toxicity observed in the urinary system of the male rat can be attributed entirely to mechanical damage from calculi. No evidence of direct kidney toxicity was shown in these studies.

In conclusion, the only toxic effect demonstrated by sodium cyanurate is the formation of "stones" in the kidneys and urinary tract of male rats and mice fed saturated solutions of sodium isocyanurate (5375 ppm) in their drinking water. Kidney/urinary tract damage occurs secondary to stone formation and is mechanical in nature. This effect does not pose a risk to individuals using swimming pools treated with chlorinated isocyanurates since final residual levels in swimming pools are required to be maintained between 1-3 ppm available chlorine. This level would be equivalent to 1.1-3.3 ppm trichloroisocyanurate, the most widely used chlorinated isocyanurate in swimming pools.

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* Nelson, G.D. Memo, Solubility of Cyanuric Acid and its Monobasic Sodium Salt, December 17, 1979, Monsanto.

C. SCIENCE FINDINGS

1. Human Toxicity

The isocyanurates have been divided into three groups for the purposes of acute testing based on structural and, to a lesser degree, potential/actual effects due largely to the level of chlorination of the triazine ring. These groups are: (i) isocyanuric acid; (ii) the dichloroisocyanurate group including the acid, the potassium and sodium salts, and the dihydrated sodium salt; and (iii) trichloroisocyanuric acid. A seventh compound, [mono(trichloro) tetra(monopotassium dichloro)] penta-s-triazinetrione, contains moieties in groups (ii) and (iii) and, accordingly, toxicology data required for this compound can be extrapolated from data for groups (ii) and (iii).

Since the chronic effects of chlorine to humans is well known, EPA determined that for purposes of metabolism studies as well as subchronic, chronic, teratogenic, and mutagenic testing, isocyanuric acid would be representative of all the chlorinated isocyanurates. By using the dechlorinated s-triazinetrione as the test substance, the effects of the triazinetrione moiety could be distinguished from those of the chlorine. Sodium isocyanurate was considered to be toxicologically equivalent to isocyanuric acid and, as such, was selected as a suitable test substance for the development of the toxicity data reviewed under this standard.

Acute Toxicity and Irritation Studies. The available data indicate that the chlorinated isocyanurates have low acute oral and dermal toxicity and high primary eye irritation toxicity. Acute inhalation studies are not required because vaporization and respirable dust are not expected. The dichloro- and trichloroisocyanurates are very mild primary dermal irritants and are not considered to be dermal sensitizers. Since the toxicity produced by sodium isocyanurate upon subchronic and chronic testing was only mechanical damage from calculi, primary dermal irritation and dermal sensitization studies are not required for the chlorinated isocyanurates. Delayed neurotoxicity data are not required because the chlorinated isocyanurates are not organophosphates. All acute effects data requirements are satisfied with the exception of primary eye irritation studies for the trichloroisocyanurates group.

Subchronic Studies. In 13-week studies involving dosing of sodium isocyanurate in the drinking water, the NOELs in rats and mice were 896 ppm (72 mg/kg/day) and 1792 ppm (522 mg/kg/day), respectively. The major toxic effects observed were hyperplasia of the urinary bladder and calculi in 2 of 40 male mice and hyperplasia in the lining of the urinary bladder in the male rats. A subchronic oral study in a nonrodent species is not required due to the similarity between the metabolism

of sodium isocyanurate in rats and dogs. Subchronic dermal (both 21- and 90-day) studies are not required because of the lack of toxicity observed in subchronic oral (drinking water) studies at doses far above use concentrations. Subchronic inhalation and neurotoxicity studies are not required for the reasons given under the associated acute topics. All subchronic testing data requirements have been met.

Chronic Studies. The LOEL in rats was 5375 ppm (371 mg/kg/day for males) based on decreased survival and lesions in the heart and urinary tract of males dosed in the drinking water for 2 years; the NOEL was 2400 ppm (154/mg/kg/day). Oncogenic effects were not noted at any dose in the 2-year rat study or in a 104-week mouse study involving dosing at up to 5375 ppm (1523 or 1582 mg/kg/day for males and females, respectively) in the drinking water. Note that 5375 ppm was reported to be the limit of water solubility for sodium isocyanurate. A chronic oral study in a nonrodent species is not required due to the similarity between the metabolism of sodium isocyanurate in rats and dogs. A three-generation rat reproductive study indicated a NOEL of 5375 for both reproductive and offspring effects; the LOEL and NOEL for adult toxicity were 5375 ppm and 1200 ppm, respectively. The chronic toxicity of the chlorinated isocyanurates is adequately understood. No additional chronic testing is required.

Teratogenicity Testing. The NOEL for both maternal and fetal toxicity was >5 g/kg/day in rats. In rabbits, sodium isocyanurate was not teratogenic; the NOELs for maternal and fetal toxicity were 50 mg/kg/day and 200 mg/kg/day, respectively. These studies are adequate; no additional teratology studies are required.

Mutagenicity Testing. Sodium isocyanurate is not mutagenic as determined by studies designed to detect the potential to induce gene mutation, structural chromosomal aberrations, or altered sister chromatid exchange frequency. These studies are adequate; no additional mutagenicity studies are required.

Special Studies. Metabolism studies in both the rat and dog, following administration of [^{14}C]sodium isocyanurate by the oral and intravenous routes, demonstrated rapid absorption, distribution, and excretion of unmetabolized isocyanurate. Elimination half-lives in rats were 32-43 minutes following 5 mg/kg/ I.V. or oral administration and 122-148 minutes after oral dosing at 500 mg/kg. At the 5 mg/kg dose, excretion was largely via the urine with generally <5% via the feces. At the 500 mg/kg oral dose, 55-70% (rats) or 27-86% (dogs) was excreted in the feces and the remainder in the urine. Radioactivity in tissues was less than or near the sensitivity of the method regardless of dose regimen. These studies adequately elucidate the absorption, metabolism, and excretion of the chlorinated isocyanurates. No additional metabolism studies are required.

2. Ecological Effects

Because of its known chronic effects to aquatic organisms, chlorine is considered to be of greater toxicological significance than the triazine moiety. Based on available mammalian metabolism and oral and dermal toxicity studies, the unsubstituted triazine ring is essentially nontoxic and rapidly excreted in an intact form. It is, therefore, unlikely to accumulate in mammals. Similiarly, EPA does not expect accumulation to occur in fish or aquatic organisms, both due to the fairly high water solubility of the unsubstituted ring (ca. 2000 ppm) and because rapid excretion is also expected to occur in fish and aquatic organisms. No ecological effects data are required for the triazine moiety.

To determine the effect of hypochlorous acid on aquatic organisms, trichloroisocyanuric acid (trichloro-s-triazinetrione) was selected by EPA as the single test substance to be used to represent all registered chlorinated isocyanurates. Since this compound provides the highest percentage available chlorine, it was considered to be the most toxic chlorinated isocyanurate to aquatic organisms.

Sufficient data are available to determine that trichloroisocyanuric acid is only slightly toxic to birds (LD_{50} to bobwhite quail 1674 mg/kg). Acceptable subacute dietary toxicity studies on bobwhite quail and mallard ducks indicate that trichloroisocyanuric acid is practically nontoxic to upland gamebirds (LC_{50} = 7235 ppm and >10,000 ppm, respectively). An avian hazard is not indicated by these studies; no additional avian toxicity data are required.

Sufficient data are available to demonstrate that trichloroisocyanuric acid is highly toxic to fish; the LC_{50} is 0.33-0.37 ppm to rainbow trout and 0.20 ppm to bluegill sunfish. Trichloroisocyanuric acid is highly toxic to freshwater invertebrates (LC_{50} to Daphnia magna is 0.19-0.8 ppm). Acute LC_{50} studies utilizing a chlorinated isocyanurate are not available for estuarine and marine organisms. However, EPA believes that the toxicity of chlorinated isocyanurates is due to the hypochlorous acid liberated in aqueous solution. Therefore, numerous studies presented in the Ambient Water Quality Criteria for Chlorine satisfy this requirement. LC_{50}s ranged from 0.02 ppm (rainbow trout) to 0.09 ppm (shrimp) chlorine in numerous marine and estuarine organisms (fish, crustaceans, gastropods); this is considered highly toxic.

Hypochlorous acid is also considered to be highly chronically toxic to marine and estuarine invertebrates and fish. Water concentrations of 0.003-0.085 ppm hypochlorous acid caused reduction in oyster shell deposition and altered blood characteristics in fish. A 30-day American oyster study revealed a maximum allowable toxic concentration (MATC) of 0.11-0.4 ppm hypochlorous acid. A 21-day MATC ranged from

0.11 ppm to 0.23 ppm for fathead minnow. The LC_{50} for trichloroisocyanuric acid was 0.08-0.37 ppm in rainbow trout.

EPA does not have adequate data to completely assess the chronic effects of the hypochlorous acid liberated from the chlorinated isocyanurates to aquatic organisms or to endangered species. Therefore, a residue monitoring study is being required for hypochlorous acid to determine the exposure and risk to aquatic organisms from the aquatic non-food uses of these chemicals. If toxic concentrations of hypochlorous acid are detected in effluent water, additional data will be required to determine the effects on growth and development (life cycle studies) of aquatic organisms.

Honey bee exposure is not expected to result from the registered uses of the chlorinated isocyanurates and nontarget insect studies will not be required.

3. Environmental Fate

Acceptable hydrolysis data are available for sodium cyanurate which is representative of all the chlorinated isocyanurates. Based on the lack of toxicological or ecological problems associated with the triazine moiety and the requirement for residue monitoring studies to measure hypochlorous acid activity in the aquatic environment, no additional environmental fate data will be required for the chlorinated isocyanurates.

Based on the available data, there are no apparent human exposure, groundwater, reentry, or drift issues.

D. TOLERANCE REASSESSMENT

No tolerances have been established for the chlorinated isocyanurates. Therefore, an ADI is not required and a tolerance reassessment is not necessary.

Industrial uses of the chlorinated isocyanurates in agricultural premises (including dairy milk farm equipment), in food/feed handling establishments as sanitizing solutions on food processing equipment and utensils, and on other food-contact articles are regulated by the Food and Drug Administration (FDA) according to 21 CFR 178.1010(b)(2) and (c)(2). This regulation stipulates that aqueous solutions containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium or calcium will not provide more than 100 ppm of available halogen determined as available chlorine.

The provisions of the Federal Food, Drug, and Cosmetic Act (Section 402) require the establishment of or exemption from a tolerance for the use of chlorinated isocyanurate

formulations as poultry drinking water sanitizers and as egg sanitizers. However, based on the lack of mammalian metabolism and oral and dermal toxicity demonstrated by the chlorinated isocyanurates in the studies reviewed under this standard, EPA will be willing to consider a request for an exemption from the requirements of a tolerance for these uses.

Agricultural uses of the chlorinated isocyanurates for the commercial treatment of eggs for human consumption are also regulated under the United States Department of Agriculture (USDA) egg grading and egg products inspection programs. USDA requires that to be accepted under these programs, all formulations must be in compliance with 21 CFR 178.1010 as sanitizing solutions for food contact surfaces.

E. SUMMARY OF DATA GAPS

The Agency has identified data necessary to evaluate the environmental and human risks associated with the use of the chlorinated isocyanurates and their salts. These data must be developed in order to maintain registrations of products or register new products containing these chemicals. The following table summarizes the data gaps, including product chemistry information. Please note that this is only a summary and details can be obtained by referring to Table A.

Summary of Generic Data Gaps - Chlorinated Isocyanurates

158.120 Product Chemistry

All of the product chemistry data are required.

158.145 Wildlife and Aquatic Organisms

72-7 Simulated Field Testing (Residue Monitoring) - Aquatic Organisms

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITION

Based on a review and evaluation of all available data on the chorinated isocyanurates and their salts, the Agency has made the following determinations. Refer to Section IV.D for specific language for label revisions.

1. The Agency will not place the chlorinated isocyanurates into Special Review.

Rationale: The chlorinated isocyanurates do not exceed the risk criteria for adverse effects in 40 CFR, Section 154.7. Available data indicate that the chlorinated isocyanurates do not pose a risk of serious acute injury to humans, avian species and aquatic organisms. Because animal effects were limited to hyperplasia of the urinary blader and calculi in male mice and hyperplasia of the lining of the urinary bladder in male rats at doses near the limit of their solubility, these chemicals appear to produce no risk to humans.

2. The Agency has determined that the present precautionary statements for persons handling or applying the chlorinated isocyanurates are sufficient for the labels of manufacturing-use products.

Rationale: Available data indicate that the chlorinated isocyanurates cause low acute oral and dermal toxicity (Category III and IV) and high primary eye irritation toxicity (Category I). The labeling of these product contain statements, including the signal word "Danger" because of the eye effects, that provide precautionary measures to ensure safe handling of the pesticide products and provide the user with first aid instructions.

3. The Agency has determined that nontarget insect studies are not required.

Rationale: Exposure to nontarget insect species is not expected to result from the registered uses of the chlorinated isocyanurates. Therefore, honey bee testing is not required.

4. The Agency will not impose a special label advisory statement for endangered species at this time.

Rationale: Because the chlorine released from the chlorinated isocyanurates is so volatile, the Agency does not expect exposure to endangered species from the registered patterns of use or from accidental spills. However, residue monitoring studies are being required to determine if hypochlorous acid residues resulting from the use of these chemicals may reach surface water.

If the estimated environmental concentrations of chlorine residues resulting from the use of these chemicals exceed the endangered species trigger for aquatic species (1/10 of the LC_{50}), an Office of Endangered Species opinion will be requested.

5. The Agency will not require the submission of microbiological efficacy data in support of the antimicrobial uses of the chlorinated isocyanurates.

Rationale: EPA has data in its files which adequately demonstrate the efficacy of hypochlorous acid. Therefore, no additional microbiological efficacy data will be required.

6. The Agency is requiring the establishment of or exemption from a tolerance for the use of chlorinated isocyanurate formulations as poultry drinking water sanitizers and as egg sanitizers. If such a tolerance or exemption from a tolerance is not proposed within 6 months from the date of issuance of this standard, these uses will be cancelled.

Rationale: No tolerances have been established for the chlorinated isocyanurates as poultry drinking water sanitizers or as egg sanitizers and residue data do not exist to support these uses which may result in isocyanurate residues in eggs and poultry. However, based on the lack of mammalian metabolism and oral and dermal toxicity demonstrated by the chlorinated isocyanurates, EPA will be willing to consider a request for an exemption of a tolerance for these uses.

7. While data gaps are being filled, currently registered manufacturing-use products containing chlorinated isocyanurate may be sold, distributed, formulated and used, subject to the terms and conditions specified in this standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration for previously registered use patterns simply because data are missing or are inadequate [see FIFRA sec. 3(c)(2)(B) and 3(C)(7)]. Issuance of this standard provides a mechanism for identifying data needs which then will be required to be submitted to maintain the registration of pesticide products containing chlorinated isocyanurate. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this standard, products must contain a chlorinated isocyanurate as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this standard, manufacturing-use products (MUPs) must contain one of the six chlorinated isocyanurates described in Section II (A) as the sole active ingredient. Each MUP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing chlorinated isocyanurates provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this standard, manufacturing-use products may be labeled for formulation into end-use products intended for indoor and aquatic non-food use patterns only. The Index to Pesticide Chemicals2/ lists all registered uses and sites, as well as approved maximum application rates and frequencies.

D. LABELING

All manufacturing-use products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing a chlorinated isocyanurate may be released for shipment by the registrant after 12 months from the date of issuance of this standard unless the product bears an amended label which complies with the requirements of this standard.

2/ The Index to Pesticide Chemicals may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703/487-4650).

No pesticide product containing a chlorinated isocyanurate may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person in channels of trade after 24 months from the date of issuance of this standard unless the product bears an amended label which complies with the requirements of this standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for manufacturing-use products must list the active ingredient as:

Dichloro-s-triazinetrione; or

Potassium dichloro-s-triazinetrione; or

Sodium dichloro-s-triazinetrione; or

Trichloro-s-triazinetrione; or

Penta-s-triazinetrione; or

Sodium dichloro-s-triazinetrione dihydrate.

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify site categories which are listed in the Index to Pesticide Chemicals. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements For Manufacturing-Use Products

a. Labels for manufacturing-use products containing chlorinated isocyanurates must bear statements reflecting the acute eye irritation potential (Category I) for these chemicals. Required precautionary statements associated with this category are specified in 40 CFR 162.10.

b. The signal word "Danger" is required on the front panel of all manufacturing-use labels.

c. The following environmental hazard statement must appear on all manufacturing-use labels:

> This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

V. PRODUCTS SUBJECT TO THIS STANDARD

All manufacturing-use products containing one of the chlorinated isocyanurates identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. Products are subject to the following requirements:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B3/

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

Refer to Section IX for specific submission requirements and timeframes.

3/ Data requirements are listed in the two Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption* for that active ingredient.

* If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all previously eligible producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.4/

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4/ Registrations granted after issuance of this standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703/487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Any protocol must be conducted in accordance with the Good Laboratory Practice Regulation (48 FR 53846). Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient, studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.C.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for registrants is not consistent with the Act. Accordingly, the Agency does not anticipate granting registrants permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your manufacturing-use registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard. These data are listed in Table B.

In order to comply with the product-specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review. Refer to Section IX for specific submission requirements and timeframes.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this registration standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.5/

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement, if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

e. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Product Specific Data Report (EPA Form 8580-4).

5/ If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Addresses

The required information must be submitted to the following address:

Jeff Kempter (PM 32)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

TGUIDE-1

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

D = Aquatic, non-food
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying Master Record Identification (MRID) number. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes2/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes3/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes4/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	N/A	N/A	Yes	6 Months
63-6 - Boiling Point	TGAI	All	N/A	N/A	No5/	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes	6 Months
63-8 - Solubility	TGAI or PAI	ALL	N/A	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes	6 Months
63-10 - Dissociation Constant	PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	N/A	N/A	Yes	6 Months
63-12 - pH	TGAI	All	N/A	N/A	Yes	6 Months
63-13 - Stability	TGAI	All	N/A	N/A	Yes	6 Months

1/ Not applicable. Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.
2/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to process each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.
3/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended or side) in the manufacturing process, and any contamination during and after production must be submitted.
4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.
5/ Not required because the technical material is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
Degradation Studies-Lab						
161-1 - Hydrolysis	TGAI or PAIRA	D,I	Yes	00056478	No1/	
Photodegradation						
161-2 - In Water	TGAI or PAIRA	D	No		No2/	
161-3 - On Soil	TGAI or PAIRA	N/A	No		No3/	
161-4 - In Air	TGAI or PAIRA	N/A	No		No4/	
Metabolism Studies-Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	N/A	No		No3/	
162-2 - Anaerobic Soil	TGAI or PAIRA	N/A	No		No3/	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No		No2/	
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		No2/	
Mobility Studies						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	N/A	No		No3/	
163-2 - Volatility (Lab)	TEP	N/A	No		No4/	
163-3 - Volatility (Field)	TEP	N/A	No		No4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
Dissipation Studies-Field						
164-1 - Soil	TEP	N/A	No		No3/	
164-2 - Aquatic (Sediment)	TEP	D	No		No2/	
164-3 - Forestry	TEP	N/A	No		No5/	
164-5 - Soil, Long-term	TEP	N/A	No		No3/	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	N/A	No		No6/	
165-2 - Rotational Crops (Field)	TEP	N/A	No		No6/	
165-3 - Irrigated Crops	TEP	N/A	No		No6/	
165-4 - In Fish	TGAI or PAIRA	D	No		No2/	
165-5 - In Aquatic Non-Target Organisms	TEP	D	No		No2/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

§158.130 Environmental Fate - Continued

1/ The test substance for this requirement was sodium isocyanurate which is toxicologically equivalent to isocyanuric acid, a chemical representative of all the chlorinated isocyanurates. Although isocyanurate acid is utilized as a buffer to stabilize chlorine and has no pesticidal properties per se, it was selected as the test substance for this study because by using the dechlorinated s-triazetrione, the effects of the triazinetrione moiety can be distinguished from those of the chlorine.

2/ The environmental fate of hypochlorous acid, formed upon reaction with water of the chlorine portion of the chlorinated isocyanurates, is known. In addition to hypochlorous acid, the triazine moiety is expected to result from degradation of chlorinated isocyanurates in the aquatic environment. Based on available mammalian metabolism and oral and dermal toxicity studies, the unsubstituted triazine ring is essentially nontoxic and rapidly excreted in an intact form. It is, therefore, unlikely to accumulate in mammals. Similiarly, no accumulation in fish or aquatic species is expected to occur, both due to the fairly high water solubility of the unsubstituted ring (ca. 2000 ppm) and because rapid excretion is also expected to occur in fish and aquatic organisms. As a result of the lack of toxicological or ecological problems associated with the triazine moiety, these data are not required.

3/ Not required because the chlorinated isocyanurates have no soil application uses.

4/ Not required because the chlorinated isocyanurates are always applied and used in water solution.

5/ Not required because the chlorinated isocyanurates have no forestry uses.

6/ Not required because the chlorinated isocyanurates have no crop uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral Toxicity - Rat	TGAI	All	No		No2/	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	All	No		No2/	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	All	No		No3/	
81-7 - Delayed Neurotoxicity - Hen	TGAI	All	No		No4/	
Subchronic Testing						
82-1 - 90-Day Feeding - Rodent, and	TGAI	All	Yes1/	00063477,00124782	No	
- Non-rodent (Dog)			No		No5/	
82-2 - 21-Day Dermal - Rabbit	TGAI	All	No		No6/	
82-3 - 90-Day Dermal - Rabbit	TGAI	All	No		No6/	
82-4 - 90-Day Inhalation - Rat	TGAI	All	No		No3/	
82-5 - 90-Day Neurotoxicity - Hen	TGAI	All	No		No4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
Chronic Testing						
83-1 - Chronic Toxicity - 2 species	TGAI	All				
- Rodent, and			Yes1/	00126362	No	
- Non-rodent (Dog)			No		No5/	
83-2 - Oncogenicity - 2 species	TGAI	All				
- Rat (preferred), and			Yes1/	00126362	No	
- Mouse (preferred)			Yes1/	00126361	No	
83-3 - Teratogenicity - 2 species	TGAI	All				
- Rat			Yes1/	00105168	No	
- Rabbit			Yes1/	00132510	No	
83-4 - Reproduction - Rat 2-generation	TGAI	All	Yes1/	00150286	No	
Mutagenicity Testing						
84-2 - Gene Mutation (Ames Test)	TGAI	All	Yes1/	00094883	No	
84-2 - Structural Chromosomal Aberration	TGAI	All	Yes1/	00091031	No	
84-4 - Other Genotoxic Effects	TGAI	All	Yes1/	00094882	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	All				
- Rat			Yes1/	00131014	No	
- Dog			Yes1/	00128287	No	

1/ The test substance for this requirement was sodium isocyanurate which is toxicologically equivalent to isocyanuric acid, a chemical representative of all the chlorinated isocyanurates. Although isocyanurate acid is utilized as a buffer to stabilize chlorine and has no pesticidal properties per se, it was selected as the test substance for this study because by using the dechlorinated s-triazetrione, the effects of the triazinetrione moiety can be distinguished from those of the chlorine.
2/ Not required because 10 daily oral doses of 5 gm/kg/day produced no toxicity in the rat teratology study.
3/ Not required because sodium isocyanurate will not vaporize and is not expected to produce a respirable dust.
4/ Not required because sodium isocyanurate is not an organophosphate inhibitor of cholinesterase, or related to such inhibitors or metabolites of such inhibitors.
5/ Not required based on comparative metabolism studies in rat and dog.
6/ Not required based on the lack of toxicity demonstrated in oral drinking studies at doses far above use concentrations.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Acute Avian Oral Toxicity	TGAI	D,I	Yes	00132603,00150962	No	
71-2 - Avian Subacute Dietary Toxicity	TGAI	D	Yes	00132426,00132427 00144301,00144302 00150963,00150964		
- Upland Game Bird, and					No	
- Waterfowl					No	
71-3 - Wild Mammal Toxicity	TGAI	N/A	No		No1/	
71-4 - Avian Reproduction	TGAI	N/A	No			
- Upland Game Bird, and					No1/	
- Waterfowl					No1/	
71-5 - Simulated Field Testing	TEP	N/A	No			
- Mammals, and					No1/	
- Birds					No1/	
- Actual Field Testing	TEP	N/A	No			
- Mammals, and					No1/	
- Birds					No1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
Aquatic Organism Testing						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and - Warmwater Fish Species	TGAI	D,I	Yes2/	00026193,00026195 00150965,00150966	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	D,I	Yes	00019383,00150967 00154329	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms - Fish - Mollusk - Shrimp	TGAI	D	Yes	40351801	No	
72-4 - Fish Early Life Stage, and - Aquatic Invertebrate Life-Cycle	TGAI	D	Partially	40351801	Reserved3/	
72-5 - Fish - Life-Cycle	TGAI	D	Partially	40351801	Reserved3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	D	No			
- Crustacean					No4/	
- Fish					No4/	
- Insect Nymph					No4/	
- Mollusk					No4/	
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	D	No		Yes5/6/	24 Months Protocol: 4 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLORINATED ISOCYANURATES

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Not required because there is no expected exposure from the registered patterns of use.
2/ Only one species is required.
3/ Development of these data is contingent upon the results of the residue monitoring study for chlorine resulting from treatment with the chlorinated isocyanurates (72-7).
4/ In addition to hypochlorous acid, the triazine moiety is expected to result from degradation of chlorinated isocyanurates in the aquatic environment. Based on available mammalian metabolism and oral and dermal toxicity studies, the unsubstituted triazine ring is essentially nontoxic and rapidly excreted in an intact form. It is, therefore, unlikely to accumulate in mammals. Similiarly, no accumulation in fish or aquatic species is expected to occur, both due to the fairly high water solubility of the unsubstituted ring (ca. 2000 ppm) and because rapid excretion is also expected to occur in fish and aquatic organisms.
5/ Simulated field testing is required as follows: Within 24 months a study monitoring chlorine in industrial effluents and receiving waters is required where the pesticide is used as a microbiocide in cooling towers, pulp and paper mills, and oil drilling operations. Based on use information (i.e., geographical sites, amount used), the registrant is required to develop an acceptable protocol, within 120 days of receipt of this notice and prior to study initiation, to sample a representative number of the above mentioned facilities in order to assess the release of chlorine into the environment with regard to the National Criteria set for this chemical. Monitoring is required due to the known acute and chronic effects of hypochlorous acid on aquatic organisms and possible effects on endangered species. Any protocol developed for monitoring this chemical must consider the following requirements: (i) use of standard analytical methods, i.e., HPLC or MSGC, to measure chlorine, (ii) sites selected for sampling must be where chlorinated isocyanurates are currently being used and be representative of small and large facilities and/or volumes, (iii) sites selected must also be representative of (a) a range in volume of the receiving water bodies of rivers and (b) freshwater and estuarine ecosystems, (iv) samples taken for analysis must be taken before treatment, after treatment and from receiving waters, (v) sampling should be done at regular intervals for a long enough period of time to account for such things as seasonal and use variations. Actual field testing for fish and aquatic species will be reserved pending the results of this study.
6/ The test material for this study is trichloroisocyanurate.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	N/A	N/A	Yes2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	N/A	N/A	Yes3/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	N/A	N/A	Yes4/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	N/A	N/A	Yes5/	12 Months
62-2 - Certification of Limits	MP	All	N/A	N/A	Yes6/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	N/A	N/A	Yes7/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	MP	All	N/A	N/A	Yes	6 Months
63-4 - Odor	MP	All	N/A	N/A	Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	N/A	N/A	Yes	6 Months
63-12 - pH	MP	All	N/A	N/A	Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	N/A	N/A	Yes	6 Months
63-15 - Flammability	MP	All	N/A	N/A	No8/	
63-16 - Explodability	MP	All	N/A	N/A	Yes	6 Months
63-17 - Storage Stability	MP	All	N/A	N/A	Yes	15 Months
63-18 - Viscosity	MP	All	N/A	N/A	Yes	6 Months
63-19 - Miscibility	MP	All	N/A	N/A	No9/	
63-20 - Corrosion Characteristics	MP	All	N/A	N/A	Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORINATED ISOCYANURATES

§158.120 Product Chemistry - Continued

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of each active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at >0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided.

7/ Analytical methods must be provided to determine the active ingredient for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ Not required because there are no flammable liquids in the product.

9/ Not required because the product is not intended to be mixed with petroleum solvents.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORINATED ISOCYANURATES

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral Toxicity - Rat	MP	All	Yes	00150953,00150959	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	Yes	00150954,00150960	No	
81-3 - Acute Inhalation Toxicity - Rat	MP	All	No		No1/	
81-4 - Primary Eye Irritation - Rabbit	MP	All	Partially	00150955	Yes2/	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	Yes	00150956,00150961	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	All	Yes	00144720,00144721	No	

1/ Not required because chlorinated isocyanurates will not vaporize and are not expected to produce a respirable dust.

2/ This study is only required for trichloroisocyanurate.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for

whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to

other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days, irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours

(i) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the

basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	8
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F. if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F. and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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OMB Approval No. 2070-0057 (Expires 11/30/89)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date _____

Registration Standard for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or-specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. _____ Product Name _____

Applicant's Name and Address _____

_____

_____

_____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): _____

_____

_____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.
_____	_____
_____	_____
_____	_____

Signature _____

Date _____ Title _____